UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,981	03/02/2007	Martin Leonard Ashdown	5517-18	8112

22442 7590 09/03/2009

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,981	ASHDOWN, MARTIN LEONARD	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-50,52-56 and 58-65* is/are pending in the application.

4a) Of the above claim(s) *48,52-56 and 63-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-47,49,50 and 58-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 45-50, 52-56, and 58-65 are pending in the application.

2. In the prior action, mailed on December 9, 2008, claims 45-66 and 72-75 were pending in the application; with claims 48, 52-57, and 63-65 withdrawn from consideration; and claims 45-47, 49-51, 58-62, 66, and 72-75 under consideration and rejected.

3. In the Response of June 9, 2009, the Applicant amended claims 45, 46, and 63-65; and cancelled claims 51, 57, 65, 66, and 72-75.

4. Claims 45-47, 49, 50, and 58-62 are under consideration.

Election/Restrictions

5. Applicant provides further arguments with respect to the restriction among the various identified methods. These arguments are not found persuasive as the present claims are still found to be anticipated by (at least) the cited WO'257 reference. The Applicant's arguments are addressed in the statement of the anticipation rejection below. As the anticipation rejection is maintained, unity is still found to be lacking.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on June 9, 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

7. **(Prior Objection- Withdrawn)** The disclosure was objected to because it contains an embedded hyperlink and/or other form of browser-executable code. In view of the amendment of the specification, the objection is withdrawn.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(New Rejection- Necessitated by Amendment)** Claims 45-47, 49, 50, 58, 59, 61, and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods wherein the agent is an agent antagonistic to the production or activity of regulator cells (i.e. the agents of claim 60), does not reasonably provide enablement for the claimed methods wherein the agent is any agent suitable for the treatment of the disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims have been amended to require that the agent is administered "when regulator cell numbers and/or activity are increasing."

With respect to this embodiment, the application teaches that the agent is an agent such as is described by claim 60. See e.g., page 7 line 29 to page 8 line 2. In contrast, the application indicates that other agents may also be administered based on the monitoring of the immune system cycling, as was previously claimed, but indicates that such other agents are administered

at different time points from that required by the present claims as amended. See e.g., pages 8-9 (teaching the administration of vaccines at the reverse point in the cycle- i.e. where the effector cell production or activity is increasing).

As the teachings of the application indicate that only the anti-regulator drugs should be administered at the particular time point identified in the amended claims, the claims are rejected as lacking adequate enabling support for the administration of any agent at this time point.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. **(Prior Rejection-Maintained)** Claims 45-47, 49-51, 58-62, 72-75 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 2003/068257 (WO'257- of record in the March 2007 IDS). The rejection is withdrawn from cancelled claims 51 and 72-75.

The Applicant traverses the rejection of the remainder of the claims on the grounds that the reference relates to the "resetting" of the immune response to the target antigen; and on the basis that the reference does not teach the cycling of the immune system. The arguments are not found persuasive. Further, the Applicant also takes issue with the Examiner's rejection of the dependent claims relating to the period during which the immune marker should be monitored. The arguments are not found persuasive.

First, the Applicant asserts that the teachings of the reference fail to teach the cycling of the immune system. It is agreed that this is the case. Nonetheless, the reference teaches the monitoring of the immune system using an immune marker (CRP) as is required by the present claims, and teachings what treatments are administered based on the levels of this marker. The reference also teaches that the monitoring should be maintained for at least a month, which would inherently detect the changes in the cycle (identified by the application as occurring every 14-15 days). While the reference teaches the resetting of the immune system, there is nothing in the present claims to exclude the use of such a step. Thus, the presence of this step in the art fails to distinguish the present claims from the method of the reference. Thus, performance of the method described by the reference would inherently result in the monitoring of the immune system cycling, and in the administration of anti-regulatory cell agents at the time point indicated by the present claims. The fact that the teachings of the reference did not recognize the repeated cycling of the immune system therefore fails to distinguish the presently claimed methods from those of the reference.

Further, with respect to the time period during which the immune marker (here- C-reactive protein or CRP) is monitored, it was noted that the reference specifically teaches the monitoring of the protein preferable at least once a day, and for a period of at least a month. See e.g., Example 4. Because the reference specifically teaches such, the reference anticipates the timing limitations of the dependent claims. The Applicant's arguments based on the teachings of the reference with respect to the need or motivation for such monitoring is noted. However, as the reference specifically teaches the monitoring as described in the claims, the arguments are not found persuasive. Further, while the Applicant asserts that the monitoring is not to determine

when the agent should be administered. The argument is not found persuasive. On pages 18-19, the reference specifically indicates that the monitoring is used to determine when the therapeutic agents are to be administered. It is noted that, if the monitoring shows the need for further "resetting" such indicates the need for the administration of the anti-regulator cell agent (i.e. the agent of interest in the methods of the present application). Thus, by teaching the performance of monitoring to determine the need for such resetting (and when it should be performed) the reference teaches the use of such monitoring to determine when an agent for controlling regulator cell expansion should be administered.

For the reasons above, and the reasons of record, the rejection is maintained.

12. **(Prior Rejection-Withdrawn)** Claims 45, 47, 49, 50, 58, 60, 62, 66, and 72-74 were rejected under 35 U.S.C. 102(b) as being anticipated by Child et al. (Cancer 45:318-26). In view of the amendments to the claims requiring the administration of a drug at a particular time point, the rejection is withdrawn.

13. **(Prior Rejection- Withdrawn)** Claims 45-47, 49, 60, and 62 were rejected under 35 U.S.C. 102(b) as being anticipated by Little et al. (Curr Opin Oncol 12:438-44).). In view of the amendments to the claims requiring the administration of a drug at a particular time point, the rejection is withdrawn.

14. **(Prior Rejection- Withdrawn)** Claim 66 is rejected under 35 U.S.C. 102(b) as being anticipated by Eda et al. (J Clin Lab Anal 12:137-44) In view of the cancellation of this claim, the rejection is withdrawn.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. **(Prior Rejection-Maintained)** Claims 45-47, 49-51, 58-62, and 72-75 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-28, 31-32, 35, 36-38, and 42-47 of copending Application No. 10/503794. In view of the amendments to the claims, the rejection is maintained as a rejection of claims 45-47, 49, 50, and 58-62 over copending claims 27, 33-35, 37, 38, and 45-47. No arguments have been presented with respect to the rejection. The rejection is therefore maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. **(Prior Rejection- Maintained)** Claims 45-47, 49-51, 58-62, 72, and 74 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 10-13, and 15 of copending Application No. 12/333/369. The rejection is withdrawn from cancelled claims 51, 72, and 74. No arguments have been presented with respect to the rejection. The rejection is therefore maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648